~~Confidential~~

Helsinki, 26 October 2023

Addressee(s)
Registrant(s) of JS_940-510-9 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
23 September 2015

Registered substance subject to this decision ("the Substance")
Substance name: Bis(2-propylheptyl) hexanedioate
EC/List number: 940-510-9

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***2 February 2026***.

Requested information must be generated using the Substance unless otherwise specified.

Information required from all the Registrants subject to Annex VIII of REACH

1. Long-term toxicity testing on fish, also requested below (triggered by Annex VIII, Section 9.1.3., Column 2).

Information required from all the Registrants subject to Annex IX of REACH

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210).

The reasons for the request(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

In the requests above, the same study has been requested under different Annexes. This is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided. Only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report, where** relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the request(s)
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons for the request(s)

Reasons related to the information under Annex VIII of REACH

1. Long-term toxicity testing on fish

1 Short-term toxicity testing on fish is an information requirement under Annex VIII, Column 1, Section 9.1.3. However, long-term toxicity testing on fish may be required by the Agency (Section 9.1.3., Column 2) if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

1.1. Triggering of the information requirement

2 In the provided publication (2002), the saturation concentration of the Substance in water was estimated to be around 0.044 µg/L.

3 Therefore, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

4 In your comments to the draft decision you agree that the Substance has to be regarded as poorly water soluble.

1.2. Information requirement not fulfilled

5 The information provided, its assessment and the specifications of the study design are addressed under request 2.

Reasons related to the information under Annex IX of REACH

2. Long-term toxicity testing on fish

6 Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

2.1. Information provided in your registration dossier

7 You have provided:

(i) a long-term toxicity study on fish (OECD TG 215, 2015) with the Substance;

2.2. Assessment of the information provided

8 ECHA Guidance R.7.8.4.1 indicates that OECD TG 210 is the most suitable test guideline for addressing long-term toxicity on fish for most substances whereas the Fish, Juvenile Growth Test (OECD TG 215) is only regarded as an acceptable test method if the following cumulative conditions are met:

- there are well founded justifications indicating that growth inhibition is the most relevant effect in fish, and
- the substance has a log Kow < 5.

9 None of these conditions are met in this case. There is no justification indicating that growth inhibition is the most relevant effect in fish and the log Kow of the Substance is estimated to be over 10 based on a QSAR study and an OECD 117 study.

10 In your comments to the draft decision you agree that the OECD 215 study provided does not fulfill the information requirement of the endpoint of long-term toxicity on fish.

2.3. QSAR or (alternatively) read-across adaptation in your comments on the draft decision

11 In your comments to the draft decision, you indicate your intention to adapt this information requirement by applying a (Q)SAR approach in accordance with Annex XI, Section 1.3 or alternatively by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

2.3.1. QSAR adaptation rejected

2.3.1.1. The substance is outside the applicability domain of the model

12 Under Guidance on IRs and CSA R.6.1.5.3., a prediction is within the applicability domain of the model, when, among others, the substance and the structures selected for the prediction fall within the descriptor, structural, mechanistic and metabolic domains.

13 Your registration dossier provides the following information:

(i) The Substance and its impurities have a log Kow of 10 or above.

14 The ECOSAR Ester Fish ChV model covers a log Kow up to 8.4, as reported by you in Attachment 9.

15 You also state that "Data are available in this document for the fish chronic SARs that encompass the log Kow and MW of the registered substance. These data indicate no effects at saturation, and as such cannot be included in the regression equation but support that

the domain of the model is considered to be larger than the descriptor range of the training set."

16 The Substance and the other selected structures (for the impurities) used as input for the prediction are outside the applicability domain of the model because they have a log Kow of 10, higher than 8.4.

17 We also note your statement. However, these data are for Ester ECOSAR models for other endpoints, and not for fish ChV and you have not demonstrated in any case that fish ChV allows such considerations in relation to its applicability domain.

2.3.1.2. Conclusion on the (Q)SAR adaptation

18 Based on the above, your (Q)SAR adaptation under Annex XI, Section 1.3. is rejected.

2.3.2. Read-across adaptation in your comments on the draft decision

19 In the comments to the draft decision, you indicate that if ECHA rejects the (Q)SAR adaption under Annex XI, Section 1.3, you intend to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

20 You provided a new read-across justification document in your comments.

21 You explain that you intend to predict the properties of the Substance from information (OECD 210 study) to be obtained from the following source substance (analogue):

- bis(2-ethylhexyl) adipate ("DEHA," EC 203-090-1, CAS 103-23-1)

22 You provide the following reasoning for the prediction of aquatic toxicity: "*The target substance dipropylheptyl adipate (DPHA) is a diester of 2-propylheptanol and adipic acid, while the source substance diethylhexyl adipate (DEHA) is a diester of 2-ethylhexanol and adipic acid. Taking into account the stoichiometry in both substances, the structural difference between the two alcohols leads to the heptyl diester with a 2-propyl side chain and in the source substance to the hexyl diester with a 2-ethyl side chain. The target and source substance are considered suitable for the analogous approach due to their structural similarity. The substances share similar, if not identical, physico-chemical (Table 1) and environmental fate properties. In general, same structural components and physico-chemical properties can be considered as predictive for a great similarity of the (eco)toxicological profiles which is confirmed by available aquatic short-term and long-term toxicity studies where no toxic effects were observed for both substances in the range of water solubility. Furthermore, due to the shorter main and side chains of DEHA, it can be expected that DEHA is slightly more water soluble and consequently better bioavailable. For these reasons, the read across can be considered a worst-case scenario für DPHA.*"

23 ECHA understands that your read-across hypothesis as described in your comments assumes that different compounds have the same type of effects. You predict the properties of your Substance based on a worst-case approach.

2.3.2.1. Absence of source study

1 Annex XI, Section 1.5 of REACH requires robust study summaries for each source study.

2 Your strategy relies on source data, which are yet to be generated, so no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

2.3.2.2. Conclusion on the read-across adaptation

3 Based on the above, you have not established that relevant properties of the Substance can be predicted from data on the source substance. Your read-across approach under Annex XI, Section 1.5. is rejected.

24 Therefore, the information requirement is not fulfilled.

2.4. Study design

25 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

26 The Substance is difficult to test due to the low water solubility (0.044 mg/L) and adsorptive properties: log K_{oc} 5.6. OECD TG 210 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 210. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2012).
***Guidance on intermediates*;** ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017).
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs; ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 12 August 2022.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the request(s).

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix 3: Addressee(s) of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third-party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1 Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries (https://echa.europa.eu/practical-guides).

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2 Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(1) Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/impurity on the test results for the endpoint to be assessed. For example, if a constituent/impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/impurity.

(2) Information on the Test Material needed in the updated dossier

- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers (https://echa.europa.eu/manuals).